TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
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STAKEHOLDERS MEETING WITH)
CENTER FOR SCIENCE IN THE)
PUBLIC INTEREST)
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UNITED STATES DEPARTMENT OF AGRICULTURE

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Training Room 1
4700 River Road
Riverdale, MD

Friday
February 27, 2004

The parties met, pursuant to the notice, at 9:45 a.m.

BEFORE: MS. CINDY SMITH
Deputy Administrator

APPEARANCES:

For the U.S. DEPARTMENT OF AGRICULTURE:

REBECCA BECH, Assistant Deputy Administrator
JOHN TURNER
NEIL HOFFMAN
MICHAEL WACH
SUSAN KOEHLER

Meeting with: Center for Science in the Public Interest
GREGORY JAFFE, Director, Biotechnology Project

PARTICIPANTS:

LEVIS HANDLEY
ROBYN ROSE
MICHAEL BLANCHETTE
CRAIG ROSELAND
MEGHAN THOMAS
HALLIE PICKHARD
JIM WHITE
LAURA BARTLEY

P R O C E E D I N G S

(9:45 a.m.)

MS. SMITH: Well, good morning and welcome. We will start first by introducing everyone and then we will give our background information.

MS. BECK: Good morning. I am Rebecca Bech and I am the Associate Deputy Administrator.

MS. SMITH: I'm Cindy Smith, the Deputy Administrator.

MR. TURNER: I'm John Turner. In the past, I was a biotechnologist here; and then, for awhile, I was acting in Jim White's position, which is now under Neil's umbrella, so I came from the regulatory side over. I am Director of Policy Coordination.

MR. HOFFMAN: Neil Hoffman, Director of Regulatory Programs.

MR. WACH: I'm Mike Wach. I am the Environmental Protection Specialist.

MR. ITANDLEY: I'm Lee Itandley, a biotechnologist on the staff. I started in December.

MS. SMITH: Robyn?

MR. ROSE: This is Robyn Rose.

MS. SMITH: And Christian?

MS. ZAKARKA: Chris Zakarka.

MS. SMITH: Okay. Welcome to our

Stakeholders Discussion Series on our upcoming environmental impact statement (EIS) and our revised plant biotechnology regulation. We appreciate you taking time to spend with us today, as well as bringing lots of great information for us to factor into our upcoming decisions.

The purpose of this briefing is twofold. First, we want to provide an opportunity to share information about our plans to go forward with the development of EIS, as well as revisions to our planned biotechnology regulations. And secondly, our intention is to gather diverse and informative input for us to use to support effective decision making in the development of both our EIS and our biotechnology plant regulation provisions.

We have here from BRS members of our management team as well as additional staff, when available, and other key Agency personnel such as Chris, who are supporting BRS in this effort. I wanted to point out two individuals who are dedicated to this effort on a full-time basis. First, John Turner, who you know. John is providing overall leadership for both the completion of the EIS as well as the new plant biotechnology regulation provisions.

And Dr. Michael Wach, who introduced himself

as a newly-hired environmental protection specialist with ERS. He is with our new environmental and ecological analysis unit that is headed up by Susan Koehler. Michael brings both a Ph.D. and a J.D., as well as research experience in plant pathology and science and legal experience in cases involving NEPA, the Clean Water Act, the Clean Air Act and other environmental statutes.

As you likely know, we recently participated in interagency discussions with EPA, FDA and the White House, which, while including the coordinated framework, provide an appropriate science interspaced right between the search for biotechnology. We include with that the Plant Protection Act of 2000, which provides a unique opportunity for APHIS to revise its regulations; and potentially to substantially expand our authority while leveraging the experience gained through our history of regulation to enhance our regulatory framework, particularly with an eye towards future advancements of this technology.

We also concluded these discussions with the general agreement on how you will be proceeding in terms of enhancing our biotechnology, the biotech-regulatory approach for plants. Still, there is much

opportunity for public and stakeholder input in the process that we are undertaking as we look to developing the specifics of our regulatory enhancements.

Given this, what we would like to do in these meetings is have an opportunity to hear your thoughts. We are in a unique position to have very open input into our process, as we are not in the formal rule-making stage of our regulation development.

Our discussion will be professionally transcribed today for two reasons. First, we want an accurate record of your discussions, one that facilitates our ability to capture and refer to your input all through the rest of this process. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making available, as part of the public record and potentially on our Web site, documentation of all these gatherings, so that each stakeholder will have the benefit of the information shared with each of the others at this conference.

I need to acknowledge that we are in litigation with you; and, as such, that has limited somewhat our ability to speak to important segments

such as this without our lawyers. However, your input is very valuable to us. So what we look forward to doing today is having a very productive listening session. We are here to listen to your input, to capture it on the record; and have it for you to refer to.

Finally, since it will be hard to predict what the final regulation will look like that will emerge from this process, I would like to briefly share with you our overall ERS priority areas of emphasis, which we use to set direction and help ride the development and implementation of regulatory policy strategies and operations.

First, Rigorous Regulation: Rigorous regulation, which thoroughly and appropriately evaluates and insures safety, is supported by strong appliance and enforcement. Secondly, Transparency: Transparency of the regulatory process and regulatory decision making to stakeholders and the public. We feel this is critical to public confidence. Third, a science-based system insuring the best science issues to support regulatory decision-making to assure safety.

Fourth, communication, coordination and collaboration for the full range of stakeholders. And

finally, international leadership: assuring that international biotechnology standards are science based; supporting international regulatory capacity building; and considering international implications in policy in regulatory decisions.

As we enter the discussion, I would just let you know that the first time you speak, if you can precede your first comment with your name for the purposes of the transcriber; and just to remind you that we will all be speaking into microphones for the purpose of recording this for the public record.

With that, I will open the floor to use this time in any way that you would like, and to share as much information as you would like to. You don't have to speak right into it. It is on the table.

MR. FREESE: Yes. My name is Errol Freese. In my presentation, I peppered it with a number of questions from verification of certain terms from the Federal Registrar notice, but I will just have to assume that I understand what those terms are at a later time.

MS. SMITH: Actually, the way that the Center for Food Safety handled that was they just stated what the questions were and kept going; and then we can kind of make a note of those.

MR. FREESE: Okay, all of them.

MS. SMITH: Just go ahead and mention what they are. At least you have question about what kind of track and see the schedule and clarification, too.

MR. FREESE: Okay. Just to calculate into this, I guess on the first section, I was wondering about including the noxious weeds in the definition under the category of what APHIS regulates here. I was just wondering what you were thinking of? If there would be, for instance, herbicide-resistant volunteers that could become passers such as the resistant canola in Canada, I guess would be an example.

And then, related to Question 5, I guess you were including the plant products, the non-viable plant material under the definition of noxious weeds. I would make a clarification on that.

Then I am wondering where would weedy relatives that might be endowed with beneficially engineered traits, where would they fit into the regulatory framework? Again, an example here, might be that you have herbicide-tolerant rice, which may perhaps be the herbicide-tolerance traits that could get into a related wheat species. If that would somehow fit into any of your categories for regulation?

Then, on biological-control organism, I want to have a clarification on that as well. The one that came to mind perhaps was the genetically engineered insect, engineered for sterility here versus something along those lines?

MS. SMITH: I guess on my comments, I would like to start with Section 7 because that is one of the ones that raises the most concern for Friends of the Earth, an adventitious presence. The proposal here seems to be APHIS's attempt to implement the August 2002 OSTP policy directive on adventitious presence. In that document, you are directed "to provide criteria under which regulated articles may be allowable in commercial seeding commodities, if they pose no unacceptable environmental risk."

I guess to your questions, I would just state our position: We would not support establishment of a separate component in the regulatory system to address adventitious presence; hence, we would urge you not to exempt adventitious presence, at whatever level, from APHIS regulation. The rationale for that I think is just pretty basic. APHIS regulates experimental genetically engineered crops; and these crops are grown under notification or permit, in part, to evaluate their potential environmental impacts.

So, from the very first, to provide any tolerance allowance for the presence of experimental GE plant material in commercial crops: food, feed or seed, before you have conducted the environmental assessment that comes at the time that the petitioner applies for deregulation, it prejudges the outcome of that environmental assessment.

I guess, in other words, such a premature tolerance setting or allowance would be tantamount to a finding of no significant impact for, again, experimental GE crops for which all the field-trial data is not in. This possible scenario in which an experimental GE crop containment, exempted from APHIS regulation under this adventitious presence clause, is later found to have a significant environmental impact in the environmental assessment that you conduct when the crop is considered for deregulation.

So, at that point, the trait would be out of the bag and would be in the environment. Yet, you would have found formally, at the time of deregulation, that this trait does have a significant impact and shouldn't be out there, but it would be too late perhaps to do anything about it.

In this connection, I think that it is interesting to look at the fate of genetically

engineered traits in the environment, say a low level of a certain experimental trait did get out into the environment to contaminate a conventional crop.

I think the conventional wisdom is that: Unless such traits offer some kind of a selective damage, they would eventually disappear. But it is interesting to have it here, a presentation by Normal Ellstrand, who is a leading geneticist. He has a more nuanced view of this and I think that it is kind of interesting. He looks at two situations, one where you have a single gene-flow event; and the other where you have a recurrent gene-flow that would, I guess, be the situation where you have repeated field trials of the same sort of plant.

According to him, he has looked at gene crops to which gene flow pretty carefully. If the trait is neutral, it could persist. Okay, with the single-gene-flow event, a neutral trait could persist. So I guess the metabolic cost may not be significant enough to eliminate it from the population. Of course, if it offers any advantage, it could increase over time; decrease only if it is detrimental. But if you have a recurrent gene-flow, which I think is the more interesting situation, it could increase over time if it is beneficial or if its neutral.

So even a neutral trait that gets out into a related wheat species say, could increase over time even if it were neutral. I think that that is a concern; and it could persist even if it is detrimental if you have repeated introductions. So I think that should be kept in mind when we are talking about adventitious presence.

Now, some other problems we have with this is just the notion that this intermittent and low-level assumption, I think, needs to be very carefully looked at. One of the questions that I would have is: Are you going to establish numerical tolerances for adventitious presence? Is it going to be a general tolerance for all adventitious presence of any traits, or is this going to be done on a case-by-case basis? Is there going to be any assessment to establish whether adventitious presence is allowable for certain crops and, if so, at what levels?

I know that at the OTSDP meeting that was called when that directive was first put out in August 2002. Cindy you were there. I asked James White about this and the thinking at that time seemed to be that there would be no limit to the level of contaminant if permit conditions were followed. I guess the assumption there is that if permit

conditions were followed, there wouldn't be any adventitious presence.

But you get into circular reasoning here. I think it is clear that just the fact that this proposal is being put out there is an admission that adventitious presence does occur. And we would be strongly against --- well, we don't think adventitious presence should be allowed and certainly it shouldn't be allowed to be any level, just based on following permit conditions, because I don't think that those permit conditions have been validated or perhaps even can be validated under environmental conditions which vary widely.

I guess another comment is: How do you propose to confirm compliance with permit conditions? Again, according to James White back at that 2002 meeting, only 10 percent of notification trials were ever inspected at all, which is a very low level. I believe that even those that had perhaps one inspection at the time, the initiation of the trial.

So there are two levels here. Permit conditions are not going to guarantee any certain low level or intermittent level of contamination. And then, even if they are, how are you going to confirm compliance with those conditions?

MS. SMITH: Bill, I am going to interrupt.

MR. FREESE: Okay.

MS. SMITH: On any of these questions where you are kind of asking, are you asking how we are going to proceed? It is useful for us if you have any thoughts on how we should be answering those questions.

In other words, how are you going to seek compliance? You would like to see us inspect 40 percent of notifications three times. On any of these, please feel free to just give us any of your thoughts on what you would like to see us do.

MR. FREESE: Okay. One way that you might be able to see how good these permit conditions are and to test compliance with them is to use strip tests. I have suggested this before in other comment notes. Perhaps before field tests take place, the manufacturer should make available strip tests to test for the protein to test neighboring crops, or whatever, to see if you were actually getting in contamination. I don't believe that has ever been done from my understanding.

I think that that is actually really necessary, especially given that we have the incidents in Hawaii, for instance, where there has been

contamination of neighboring crops. This was under trials that were both somewhat under EPA jurisdiction and PIPS. I think one trial was over 10 acres, so that was the EPA; and one was under, so that was USDA. I forget the exact details but that seems to have been the exception that sort of testing.

Then, I would mention also adventitious presence in seed contamination is a particular concern. The Union of Concerned Scientists has put out a report that perhaps you have seen, which documents a pretty high and unexpected level of seed contamination with genetically engineered traits. One very striking example that we found a number of years ago was the Starlink. Well, actually, the USDA discovered this.

In order to get rid of the Cry 9C trait from the commercial-seed supply, USDA invited firms to have testing done. We have those 270 seed companies that had never dealt with Starlink and this is what I find interesting: They had never sold Starlink. They had these tests done and nearly a quarter of those companies found the Cry 9C trait, at some level, in some of their commercial-seed lines. To me that is very striking. How did that happen? These are companies that never sold Starlink.

So, this raises a lot of concern on a number of levels because: With contamination at the seed level, there is nothing you can do. There is nothing a farmer can do to avoid that. You can talk about pollen flow and all these other concerns, but if your seed is contained then what can you do? So confidence in the seed supply is extremely important I would think.

Then you mentioned international considerations I believe, Cindy. The economic impacts of allowing adventitious presence, I think, require a lot of consideration. You can legislate, you can legalize adventitious presence, but that is not going to force markets to accept contaminated seeds or crops. All right.

And we know that export markets here and in Japan are extremely sensitive to genetically engineered foods in general. Even if they have been deregulated in the United States, their sensitivity is going to be much greater for experimental traits.

So I would, again, strongly urge you not to allow adventitious presence. I think we need to have zero tolerance for all of these experimental traits, for all of the reasons that I have mentioned.

Then, I guess, next I wanted to move to

Section 2. Some of this applies to Section 10 as well about the tiered-risk category section. I guess our Friends of the Earth would urge that the low-risk categories, so called, are not exempted from permitting requirements; and that all genetically engineered crop trials should meet the criteria proposed for the highest-risk category. That is: the PMPs and the industrial compounds.

I guess the rationale for this is somewhat similar to the argument for adventitious presence. It seems that in order to define certain product types as low risk, moderate risk or high risk, is premature because, again, these are experimental crops. You haven't done environmental assessments on them. So to make a prejudgment as to the level of risk is, again, premature. You don't have the data.

Then I wanted to ask you to give examples of product types that you were thinking about here. The one that came to mind perhaps that you might be thinking of as a low-risk category would perhaps be: herbicide tolerance. If that were the case, if herbicide tolerance is a "product type," it would presumably encompass glyphosate, glufosinate tolerances well as resistance to 2, 4-D or any other herbicides. I don't know exactly what is in the

works.

My point here is: The resistance mechanisms for each of these different herbicide tolerance traits are completely different. They vary widely and I just wonder: What is the scientific justification for considering this heterogeneous group to pose a similar degree of risk if you have completely different mechanisms? And even if you take a narrower product type, such as glyphosate tolerance, even there you have completely different mechanisms: the EPSPS enzyme, which is insensitive to glyphosate; and, on the other hand, you have the glyphosate oxido-reductase, which degrades glyphosate.

So, again, even within the most narrowly construed product type, you have very different mechanisms. I just wondered that if a third mechanism was developed, if it were completely different, a completely different mechanism, would this automatically qualify for this particular product type and what would be the scientific justification for doing that?

I guess what I am trying to get at here is I just think again the whole idea of making prejudgments about the level of risk, without the data from the field trials, is premature. I guess one way that you

might want to define a product type is on a supposed history of safe use. You could say: Well, gylphosate resistance is proven low risk in soy beans.

In my view, this has not been demonstrated but you might make that argument. So, based on that, you might say that all experimental glyphosate-resistant crops will be classed as low risk.

But, again, here we are dealing with recombinant DNA techniques. Each genetic transformation event is unique and has its own set of unintended effects. Some of them will be quite subtle, perhaps there won't be so many with signs of others. But the point is that each event is unique and cannot -- that prevents you from tracing these crops in certain product types. I think that's why people always talk about case-by-case assessment. That always is what the industry and government have both said: These crops need to be evaluated on a case-by-case basis because these techniques are unique and non-repeatable, each event.

So it seems to me that that just invalidates the whole notion of product type and this prejudgment as to risk. I think this becomes especially true when you look at the paucity of data that is collected at the field-trial stage. And with notification trials,

it is very abbreviated; and I don't think that you collect a whole lot more for the permits.

I will just give you one example: The herbicide-resistant sugar beets that were deregulated. I forget but I think that this was in the late '90s. They contain a fusion protein that is expressed by a stretch of DNA composed of a truncated glyphosate oxido-reductase, a gene fused to sugar beet DNA. This, of course, is a result of breakage of the transformation factor in them, the holistic transformation process. So, you have a novel protein expressed. The FDA called it: Protein 34550.

This is just an example of how you can get a completely unexpected event. Now, these sugar beets were apparently glyphosate resistant, but what does that tell you about the hidden environmental risk of this novel protein? So, again, I would urge that all field trials be regulated according to the highest standards that you are talking about for pharmaceutical or industrial crops.

On Section 3, let's see: Continuing regulation in some cases rather than just complete deregulation. I think this is a good idea. I think this was suggested by the National Academy of Science Committee that, in some cases, APHIS shouldn't have an

absolute deregulation, but rather, I guess, a conditional deregulation. Actually, I think that should be the norm rather than the exception.

One case where this might be important is where regulation should continue beyond the deregulation stage. Maybe we need other terms here in this case for herbicide-resistant traits, for instance. In Canada, we have the development of doubly and triply resistant canola, which, according to the Royal Society of Canada, is becoming one of the biggest weed problems in western Canada. That's huge. They found one, some volunteer canola plants that were resistant to gylphosate glufosinate, and imidazolinone, I believe it is.

That is unacceptable. I know that in the case of rice, there is a Libertylink rice, a glufosinate-resistant rice that has already been deregulated a number of years ago. I believe in the deregulation notice, APHIS states that I believe there are two others that are under development. One is Monsanto's glyphosate-resistant rice. Then, I believe, a third.

Well, first of all, APHIS admits, in this environmental assessment, that this trait will get into weedy red rice and that people can just use other

registered herbicides if that is to occur. I think there needs to be a stricter standard here, especially when you consider that there might be others coming along, other herbicide resistant traits. Because then it seems like you are setting yourself up for possibly a situation as in Canada with the canola.

In addition to continuing regulation, perhaps APHIS should retain the authority to cancel registration. So that if problems come up, for instance, this herbicide-resistance problem, especially double or triple resistance; and then I believe in the deregulation that the original transformation event is deregulated along with all of its progeny. I think that is the standard term.

I believe NAS raised a question as to: Whether there shouldn't be continued regulation to look at stability of the integrated DNA after many generations of breeding into multiple hybrids for example. So that would be another possible case where you should use this Section 3 clause.

On Section 3, just a couple of questions. How do you define minor-unresolved risk? I am sure that you have had that question before.

I guess I will jump here to maybe Section 6. Just some clarification questions here. You are

talking about establishing a separate mechanism for regulating PMPs or IC crops grown under confinement conditions with governmental oversights, rather than using the approval process for unconfined releases. I guess I am a little confused as to terminology. I thought that all field trials basically -- well, first of all, there hasn't been an environmental assessment of a PMP field trial since 1998.

My understanding is that the legal basis for that is that these trials have just been defined as confined or contained, so exempt from, I believe, it is NEPA. So I am wondering: What does unconfined mean here in this context? Perhaps you are using it in a non-technical sense to mean an open-air trial. Does that make sense?

MR. TURNER: Which number?

MR. FREESE: This is No. 6. Because my first thought when you used the term "under confinement conditions," I interpreted that to mean greenhouse or other underground mines or some of the other mechanisms that have been proposed. So, first of all, I would like a clarification of that; and then when you say rather than use the approval process for unconfined releases, that is why I assumed the proposal referred to true containment in greenhouse or

underground mines. I hope that I am making myself clear.

In any case, I think it is a very good idea to consult with the states in this case, as well as in all cases. I think there should be closer collaboration with the states on all genetically engineered field trials, especially the high-profile kind of pharmaceutical and industrial crops. I know that in a number of states there is growing concern about what these trials might mean for the state's agriculture if containment isn't absolutely 100 percent.

One recommendation that we would have is -- and I am not a lawyer: But I think states should be given explicit authority to reject disapproved field-trial applications in all cases of experimental gene-crop trials, especially the pharmaceutical and industry compound crops.

Then, also, I think that some mechanism is needed to inform and consult with local authorities, neighboring residents and farmers, or their representatives, about any experimental GE field trial, again especially the pharmaceutical or industrial crops; and that trial should proceed only with the approval of the stakeholders.

There is actually precedence for this in the very first bio-pharmaceutical crop field trial in 1991. It was a trichosanthin-producing tobacco. North Carolina set up a genetic engineering review board to help review the application. I don't know the details of that mechanism, but it seems valuable to have true consultation with the state.

Another example is: in Colorado a review committee has been set up. It is, in my view, much too narrow. I believe it is three scientists from the university setting. So maybe this is the state's responsibility to do it, but APHIS I think should allow for it at least.

Then, Section 8, I guess I have the same objections to: How do you define low risk without field-trial data? Also, the idea of regulatory approval in a foreign country. Should APHIS provide for expedited review, or exemption from review, of certain low-risk genetically engineered commodities intended for invitation that have received all necessary regulatory approvals in their country of origin?

Again, you have the general problem with: How do you define low risk? In this case, we don't know anything about really the regulatory approval

process in a foreign country. It could fall far short of U. S, regulatory standards. I don't think we should allow that. I think that there should always be a separate APHIS assessment.

Section 4, I guess would be the final section. The position of Friends of the Earth: We support a ban on all open-air plantings of all crops genetically engineered to express pharmaceutical proteins, industrial compounds or other proteins that are not intended for the food or feed chain; and whether these crops are food crops or non-food crops? We believe that most cultivation of non-food crops engineered to express such proteins should be allowed under: proving 100-percent containment.

Food-safety evaluations are not appropriate for crops engineered to express these non-food proteins and should not be used to justify tolerances. That is the thought in this section about food-safety evaluation. Zero tolerance is the only acceptable standard.

In referring to Section 4, you ask: How should the results of the food-safety evaluation affect the review permit conditions and other requirement for these plants? We don't think that these crops should be even evaluated for food safety.

They are not meant for food; they have no business in food meeting the zero-tolerance standard.

Now, also, it seems to be more of an FDA question, so I was kind of puzzled to see it here in this foreign notice. This raises another question about: How we define pharmaceutical and industrial crops; and should there be a category, for instance, for non-food proteins? Because pharmaceutical and industrial proteins do not cover the universe of these genetically engineered proteins that are not meant for food use.

There is the category: novel protein. I handed out some recommendations that have become comments that I submitted back, I believe, March of last year. The novel-protein phontoytpe where does that fall? Are all novel proteins -- again, I am talking about on the APHIS Web site, the phenotype novel protein. Are all of those considered industrial proteins, some but not others?

We need to have a consistent system. When you put a phenotype up on your Web site, we should be able to know what category that falls into in terms of your regulatory system? Does that make sense?

So, for instance, like a novel protein I found once that laccase, which is an industrial enzyme

that had been classified as a novel protein. That was one that actually -- you did change after I pointed that out. There could be many other examples that I haven't seen, but it seems to me that you need to cover these pheno types and make it clear where they fall. Are they permitted? Are these permitted pheno types, or notification pheno types? Are they non-food proteins or food proteins?

This would help with transparency, too, so that groups like ours can go to your Web site and know what we are dealing with, I guess. Again, just novel protein, too -- I mean all of these proteins are novel proteins, right? When you produce a human or animal, for instance, antibody on a plant, it is a novel protein and it is going to be a little different than the original. So it is really a meaningless category and I urge you to get rid of it.

Then the other thing is: these are comments that you made before but with pharmaceutical protein. You have two different phenotypes. Okay, let's take three: pharmaceutical, antibody and antibiotic. Those are different categories. Yet, antibodies and antibiotics are obviously pharmaceutical in nature. So, again, if someone goes to your Web site and clicks pharmaceutical protein, they are not going to get

antibodies, and there could be others too.

So, again, that is a big transparency problem because we should be able to go to one place and get all of the pharmaceutical proteins. That makes sense.

Another example with non-food proteins. Avidin is a good example. I just handled one of the case studies from my report back in the summer of 2002. Avidin, I believe was classified as a novel protein. I am not sure. I don't think that I ever actually found it on your database. It is being sold right now by Sigma as a research chemical. It actually causes Vitamin B deficiency. I don't think that it would necessarily fall under industrial compound or pharmaceutical. Yet, it has health impacts. It kills insects. It has environmental impacts.

What category is this going to be regulated under? We need to make sure that all compounds that potentially have these kinds of environmental health impacts are regulated under the strictest category. Right now, that seems the pharmaceutical- and industrial-compound category.

Aprotinin is another example. In, I believe it is the 2002 trial, where aprotinin is first

identified on your Web site. It is listed as pharmaceutical, which is appropriate. It is a blood-clotting protein. Yet, I know that from press accounts, field trials have been going on since 1997 or 1998. It must have been classified as novel or some other category at that time, which is totally unacceptable because it kills insects and has adverse impacts on honey bees.

An SAP to the EPA pointed to problems with ingestion of this class of protein. It is a protease inhibitor. So these kinds of compounds need to be strictly regulated.

MR. FREESE: There is another issue that might have been cleared up. I am not certain but I know that in 2001, APHIS issued a letter to companies that were doing field trials of pharmaceutical crops. And, John, we talked about this. They were able to renew their permits for, I believe, up through the end of 2003. Hence, those renewed trials were not being listed on the Web site and I am not sure if that has been taken care of.

But, in the interests of transparency, we need to know about all field trials. Whether they are being done under renewed or original permits? I guess one question: I am wondering if APHIS plans to

continue that process? For instance, do permits that you issued in 2004, can they be renewed for one or two years without being listed on the field-trial Web site, so we strongly discourage you from doing that because we need full records.

Then on the whole CBI policy, I know that orally I have been told that BRS checks -- okay, when an applicant claims something, a gene, a CBI, that the standard procedure is: Go to the literature, do a search; and if a company has, in fact, publicized this gene, then it does not qualify as CBI.

In fact, I found several examples in which that policy doesn't seem to have been followed, in which genes that have been publicized by the company are, nevertheless, listed as CBI on the Web site. One example is trypsin, which was widely publicized by ProdiGene. It is trypsin corn.

Yet, it was -- I asked Gene Light (ph) several times and I could never find out which trial this was, and it is not identified on the Web sites. So I would urge you to really publish all, and be as transparent as you can under the law. That hasn't been done up to now: Disclose the acreage for all field-trial permits. I don't think that there is any reasonable basis for claiming acreage as CBI. I know

the industry says it might indicate how far they are along in the process, but that just doesn't seem to hold water to me.

Then, the acreage-field trials by state, for a multi-state permit, would be very helpful to enable us to know: What is the acreage in various states?

Then, I guess expeditious responses to the Freedom of Information Act requests would be very helpful. Friends of the Earth filed a FOIA back in April 2001; and thus far, of the 131 permits that we were inquiring about, we have gotten information for two so far and it has been three years.

MS. SMITH: What was the subject of that FOIA request?

MR. FREESE: It was on the pharmaceutical crops. There were actually two responses. One was two files for permits. We were at the University of Wisconsin when the CBI was claimed. Then the others, apparently all had CBI at some level, so they are going back to the companies to clear the release of CBI information.

MS. SMITH: Could I ask you to send me a copy of that FOIA request?

MR. FREESE: Okay, sure. Finally, the three case studies I put out, I urge you to take a look at

them. I think they pull together a lot of information and I think they are valuable to just look at as examples of problematic crops that perhaps haven't received the regulatory attention they deserve.

I guess that's it. Thank you.

MS. SMITH: Do you have any questions?

MR. HOFFMAN: I have lots of questions but I was wondering if I am allowed to ask them?

MS. SMITH: You can raise them now.

MR. HOFFMAN: This goes back to the point about: no open-air tests, pharmaceuticals. I think we can certainly understand our concern about the food crops. But I care more about your reasoning for non-food crops not having open-air tests?

MR. FREESE: One reason is, and this wouldn't cover the universe of non-food crops, but one of the key studies is trysosantin in tobacco. This was evaluated to a virally vectored case. It was actually the very first bio-farm field trial back in 1991. It was repeated, I believe, in 1996.

Basically, the tobacco-mosaic virus was altered with the trysosantin gene from a Chinese plant added to the virus. The virus was used as a vector to infect the tobacco and TMV also infects tomatoes, peppers, all members of the solanaceous family.

So, this is an example for a non-food crop tobacco that is used to produce a pharmaceutical protein. You have potential infection of food crops with this virus. Okay, that is the viral vector.

I think there could be environmental concerns in the case of other non-food crops, even if there aren't food-safety concerns. I would point to the very high levels, especially levels that are being achieved recently. The latest record that I came upon was an entry where the rice was 45 percent of soluble protein for their lysozyme lactoferrin. That is a lot of protein. So with these increasing levels, it seems like environmental impacts become more of a concern, too. You have leakage from roots with BT crops.

There are studies showing that for hundreds of days, the BT toxin from a BT plant can leak into the soil and exist for hundreds of days and retain its insecticide-level activity. That is just one example of how a protein can get into the environment and cause problems.

MR. HOFFMAN: So, non-toxic affects.

MR. FREESE: Yes, yes. The short answer: yes. And these are bio-active molecules, so they are probably more concerned than maybe other traits.

MS. SMITH: Given the time, I think we need

to wrap up.

MR. FREESE: I just thought of a couple of more points that I could raise. One thing that really concerns me, especially with the bio-pharm and industrial crops. Actually, with all of the experimental crops, there doesn't seem to be any provisions to stop gene flow by bird or animal. That seems to be a big gap in the regulatory system.

Just as an example of this, I am looking at an article from the *Sacramento Bee* on Aventis Bioscience's trials of lactoferrin and lysozyme rice. This is a quote from the article: "The draft proposal from Aventis is light on some details, including: How Aventis will prevent birds from spreading its rice; what constitutes proper disposal of rice plants; and whether the company will notify the rice growers?

As a side note, I know that Brazil, for instance, hosted a field trial of Aventis Libertylink rice some years back. I believe it was in the late 1990s. One of their conditions was actually to have netting over the field trial to prevent birds from spreading the rice. I had never heard of that being even suggested here. Aventis didn't follow that condition and the Brazilians had the field trial burned, as a matter of fact.

I think that is a really serious concern that hasn't gotten any attention at all: animals as vectors. Also, with rice, it just strikes me that small-grain crops like this are especially bad for bio-pharmaceutical and industrial-crop applications because it is just so hard to control the seed. I believe that NAS suggested this or Norman Ellstrand mentioned this once. So that is a real concern. For instance: How can this bio-pharm rice be kept from getting beyond the field-trial site and getting into the environment?

MS. SMITH: Anything else? Go ahead.

MR. FREESE: No, I think that's it. If I forgot anything, I will include it in my comments.

MS. SMITH: Okay. Well, this has been really informative, lots of really good information, according to all of our notes; and who else we have here, we are looking forward to their comments as well.

Thanks a lot for coming in today. We appreciate it.

MR. FREESE: Thank you for having me.

(Whereupon, at 2:33 p.m., the meeting in the above-entitled matter was concluded.)

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REPORTER'S CERTIFICATE

CASE TITLE: STAKEHOLDERS MEETING WITH CENTER FOR SCIENCE IN THE PUBLIC INTEREST

HEARING DATE: February 27, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 27, 2004

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